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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,037	07/08/2003	Manfred Reiter	37974-0195	9074
26633	7590	06/02/2006	EXAMINER	
HELLER EHRLICH WHITE & MCAULIFFE LLP 1717 RHODE ISLAND AVE, NW WASHINGTON, DC 20036-3001				VOGEL, NANCY S
		ART UNIT		PAPER NUMBER
		1636		

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/614,037	REITER ET AL.
	Examiner Nancy T. Vogel	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-33 and 37-45 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 34-36 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. ____ .   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/6/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____ .                                   |

## **DETAILED ACTION**

Claims 1-45 are pending in the case.

Receipt of the Information Disclosure Statement on 4/6/04 is acknowledged.

### ***Election/Restrictions***

Applicant's election of Group XI, claims 34-36 in the reply filed on 3/17/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-33 and 37-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/17/06.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Price et al. (WO 98/15614) (cited by applicants) in view of Kistner et al. (US Patent 5,753,489).

Price et al. disclose a method of culturing cells comprising providing a culture of cells that have been grown in an animal protein free medium comprising soy hydrolysate at a concentration of about .1% and yeast hydrolysate at a concentration of 0.1% to about .8% (pages 19-20). Price et al. disclose this method is useful for culture of animal cells including human cells and kidney cells (see page 24). Price disclose the method may be used to grow and produce viruses using cell culture (page 2).

The difference between the reference and the instant claims is that the steps of infecting the cells with virus, incubating the infected cells to propagate the virus, harvesting the virus and preparing an immunogenic composition, and specifically, conducting those steps using particular viruses, is not disclosed.

However, Kistner et al. disclose a method of producing an immunogenic composition comprising virus or virus antigen, comprising providing a culture of a mammalian cells, infecting the cells with a virus, incubating the culture of cells to propagate the virus, harvesting the virus or antigen, and preparing an immunogenic composition from the virus or antigen (see col. 5-6). The virus may be orthomyxoviridae, paramyxoviridae and reoviridae, and the cells may be vertebrate cells such as VERO, CV-1, LLC-MK2, MDCK, MDBK cells (col. 6, lines 1-15).

It would have been obvious to one of ordinary skill in the art to have included the steps of infecting the cultured cells with a virus of interest, cultivating the infected cells, harvesting the virus, and isolating an immunogenic antigen therefore, as disclosed by Kistner et al., in the method of cultivating cells disclosed by Price et al., since both

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references disclose the growth of cells in culture for the purpose of producing virus or recombinant products of interest. One would have been motivated to do so by the disclosure of Price et al. that the method avoids contamination by animal proteins, and the usefulness of the cell culture method for producing virus. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

nv  
5/26/06

  
NANCY VOGEL  
PRIMARY EXAMINER